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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/686,682 | 10/17/2003 | Ritsu Yamamoto | 990075A | 8297 |
| 23850 | 7590 | 12/15/2004 | EXAMINER | |
| ARMSTRONG, KRATZ, QUINTOS, HANSON & BROOKS, LLP | | | COOK, LISA V | |
| 1725 K STREET, NW | | | ART UNIT | |
| SUITE 1000 | | | PAPER NUMBER | |
| WASHINGTON, DC 20006 | | | 1641 | |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,682

Applicant(s)

YAMAMOTO ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/241,085.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Please note that the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all correspondence regarding this application should be directed to Group Art Unit **1641**. All communications should be directed to **Lisa V. Cook**, whose telephone number is **(571) 272-0816**.

Amendment Entry

2. Applicant preliminary amendment filed 10/17/03 is acknowledged. In the amendment filed therein claims 1-7 and 12-18 were canceled without prejudice or disclaimer. Claims 8-11, 19 and 21 were modified. Currently claims 8-11 and 19-22 are pending and under consideration.

Drawings

3. The drawings were filed in the instant application were acceptable for examination.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

5. The information disclosure statement filed 10/17/03 has been considered as to the merits before First Action.

Priority

6. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. This application does not contain the required first sentence of the specification referencing application no. 09/246,085 now US Patent #6,677,123; which claims priority to foreign application no. 10-038186 filed 2/3/98. Please add to the specification.

Oath/Declaration

7. The oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02. The instant Application No: 09/241,085 and Filing Date: 2/1/1999 were not indicated in the oath and declaration.

Specification

8 The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

On page 19, line 25 "tow" should be "two". Appropriate correction required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 8-11 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 8-11 and 19-22 are vague and indefinite in reciting “specific sugar chain structure”. Since, the term is not defined in the disclosure the intended meaning cannot be established. Is it applicant intent to mean any sugar chain structure that has been previously identified or is known per se in the art or is this to encompass all the inherent sugar chain structures found in all α -fetoproteins. Please clarify.

B. In claims 8, 19, and 21 the use of the phrase “capable of recognizing” is vague and indefinite because it is not clear as to what this phrase encompasses. Will the reagent “bind” to alpha-fetoprotein or is there some other recognition parameter? It is suggested that the claims recite “binding” for clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al. (Clinica Chimica Acta, 254, 1996, pages 23-40).

Shimizu et al. teach that alpha-fetoprotein shows structural changes with malignancies. Sera samples were digested with glycosidase and examined by lectin affinity electrophoresis.

The relationship between alpha-fetoprotein (AFP) carbohydrate structures and liver diseases were elucidated by the lectin-reactive profiles and the effect of glycosidase digestion. More than 94% of the AFP carbohydrate structures found in-patients with benign and malignant liver disease were bi-antennary complex-type oligosaccharides. AFP is further taught to be an oncofetal glycoprotein with utility as a tumor marker for hepatocellular carcinoma and yolk sac tumor. See abstract and page 24.

Several lectin reagents are used to detect alpha-fetoprotein. They include the ones recited by applicant in claim 10. On page 25 section 2.2; *Lens culinaris* agglutinin-A (LCA), erythroagglutinating phytohemagglutinin-E₄ (E₄-PHA), and concanavalin A (con A) are disclosed as useful AFP detection reagents. Also see Tables 1-5. The lectins were also taught to detect biantennary sugar chains (claim 9).

With respect to the reagents being applicable in chromosomal abnormality, it is noted that this property is deemed inherent to the product.

II. Claims 8-11 are rejected under #5 U.S.C. 102(b) as being anticipated by Katoh et al. (U.S. Patent#5,591,589).

Katoh et al. (5,591,589) show a process for separating and measuring glycoproteins. The glycoproteins are distinguished by different sugar chain structures but have substantially the same protein structure. The researchers employed a combination of a lectin capable of recognizing the specific sugar chain of at least one glycoprotein to be measured in combination with at least a first antibody that binds to all forms of the analyte.

The combined measurements are utilized in detecting differences and identifying the glycoprotein of interest. See column 2 lines 6-26.

In example 1, beginning in column 14 line 37; reagents for measuring AFP sugar chains are taught. The lectin employed is (LCA)-A, a first anti-AFP monoclonal antibody (which binds all forms of AFP)/Applicant's 2nd antibody, and a second anti-AFP monoclonal antibody (having an antigen recognition site different from the first antibody)/Applicants 3rd antibody.

With respect to the reagents being applicable in chromosomal abnormality, it is noted that this property is deemed inherent to the product.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

III. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katoh et al. (U.S. Patent#5,591,589) in view of Foster et al. (U.S. Patent#4,444,879).

Please see Katoh et al. as set forth above. Katoh et al. disclose 3 reagents having utility in AFP detection. They employ a combination of a lectin and two anti-AFP antibodies. Katoh et al. do not specifically recite that the second antibody/Applicants 1st antibody has a high reactivity with an alpha-fetoprotein that does not bind the lectin or the first antibody/Applicants 2nd antibody.

However Katoh et al. disclose that the reaction conditions and reagent concentrations may be varied (are not critical) as long as they do not inhibit complex formation. Column 6 lines 23. Katoh et al. also disclose that the second antibody binds the antigen (AFP) at a site different from the 1st antibody. Column 14 line 65 through column 15 line 4. Therein reading on the "low reactivity" with specific AFP bound to the lectin because lectin could also occupy the antigen-binding site recognized by the second antibody/Applicants 3rd antibody.

Although Katoh et al. teach the reagents required by the claims, they do not specifically teach the inclusion of all the reagents in kit configurations. In other words, the reference fails to teach all the reagents as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe kit configurations. In their patent kits including the reactant reagents, a micro plate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Katoh et al. and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

12. For reasons aforementioned, no claims are allowed.

Remarks

13. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Arab et al. (American Journal of Human Genetics, 43(3), 9/1988p.A225, Abstract No. (0896) 163.6) disclose maternal serum test that measured the concentration of both beta chorionic gonadotropin (MSHCG) and alpha-fetoprotein. The tests were shown to be suitable prenatal screening tools for Down's syndrome when utilized as independent events. On the other hand, superior sensitivity and accuracy was achieved when a combination of the two proteins were evaluated in maternal samples and correlated to the risk of a fetus having Down's syndrome. This reference links alpha-fetoprotein measurement to fetal chromosome abnormality.

14. For reasons aforementioned, no claims are allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

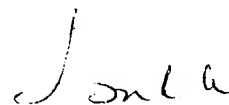


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12/10/04



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